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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/450,488 11/29/99 LEBNER M 0156-2002

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EXAMINER

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ART UNIT

PAPER NUMBER

3761

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04/06/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/450,488	LEBNER, MICHAEL
	Examiner Kim K. Lewis	Art Unit 3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 17 January 2001.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-21 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

15) Notice of References Cited (PTO-892)

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

18) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

19) Notice of Informal Patent Application (PTO-152)

20) Other: *Detailed Action*.

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## **DETAILED ACTION**

### *Response to Amendment*

1. The amendment filed 1/17/01 has been received and made of record in the application file wrapper.

### *Information Disclosure Statement*

2. The IDS papers filed 2/17/01 have been received and made of record in the application file wrapper.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 4, 5, 8-12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,263,970 ("Prellar").

Regarding claim 1, Prellar substantially anticipates all features of the claimed invention including a first strip (12), a second strip (14) having adhesive (18), connectors (limbs 24.1, 26.1),

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pulling elements (24, 26) and means for attaching the connectors to the first and second strips<sup>1</sup>.

It should be noted from the drawings that the device is inherently flexible since the connectors fold over and are secured at the pulling elements. Preller fails to teach the connectors

Regarding claim 2, Prellar teaches the strips are made of synthetic plastic (column 2, lines 7-10).

Regarding claim 4, note Fig. 1 of Prellar which discloses interleaved connectors.

Regarding claim 5, note Figs. 1-5 of Prellar which shows the first elongated connectors adjacent one another and centrally located, and second elongated connectors flanking the elongated connectors at outside edges.

Regarding claim 8, the examiner contends that the elements disclosed in Prellar are capable of being cut from sheet stock since nothing in Prellar precludes such a step of forming the device. Applicant should note that step of manufacturing does not propose any structural limitations in the claim.

Regarding claim 9, Prellar discloses wound healing, note Fig. 3.

Regarding claim 10, Prellar discloses curved edges on the strips (50, 52) column 3, lines 47-51).

Regarding claim 11, and the cut-away portion note Fig. 6 of Prellar.

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<sup>1</sup>The adhesive on the lower surface of the pulling element attaches the connectors to the first and second strips.

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Regarding claim 12, as broadly claimed, Prellar discloses all features of the claim including a device adapted for wound closure alignment since it is semi-transparent.

Regarding claim 14, as can be seen in Fig. 6 of Prellar, the device when in use is adapted for drug delivery in that a drug may be delivered to the wound/incision.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 3 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,534,010 ("Peterson").

Regarding claim 1, Peterson anticipates substantially all features of the claim including a first and second strips (12 and 14) having an adhesive lower surface (column 3, lines 11-14), a plurality of connectors (filaments 46, 48), pulling elements (16, 18). It should be noted that the device is flexible since the tapes are elastic. Peterson fails to teach means for attaching the first and second connectors to the first and second strips. Instead, Peterson discloses adhesive means for connecting the pulling elements to the first and second strips. Absent a critical teaching and/or a showing of unexpected results derived from attaching the connectors to the first and second strips, the examiner contends that such a modification is an obvious design choice. The examiner

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further contends that since the connectors (filaments) are connected to the pulling element which are attached to the first and second strips via adhesive, the device of Peterson performs equally well.

Regarding claim 3, Peterson teaches removal of elements (32, 34).

Regarding claim 17, note the stiff cylindrical member (116) and polyamide members (50, 52).

Regarding claim 18, the method as claimed is accomplished by placing the device of Peterson on the user.

Regarding claim 19, note Figs. 1-4 which show the steps of pulling the pulling elements and then removing them as the device is placed on the user.

6. Claims 1, 18, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,423,731 ("Roomi").

Regarding claim 1, Roomi discloses a device for wound/incision closure comprising: adhesive first and second fabric strips (16) which are inherently flexible; first and second pulling elements (22); and elongated connectors (20). Roomi fails to teach means for attaching the connectors to the strips. Absent a critical teaching and/or a showing of unexpected results derived from attaching the connectors to the first and second strips, the examiner contends that such a modification is an obvious design choice.

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Regarding claim 18, the method of the instant invention is practiced by mere application of the device of Roomi.

Regarding claim 20, as can be seen from Figs. 9 and 10, the pulling elements are secured to the skin.

Regarding claim 21, as can be seen from Fig. 5 of Roomi, the connectors are sufficiently spaced-apart to facilitate lateral adjustment of the first and second strips.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prellar.

Regarding claims 6 and 7, Prellar fails to teach that the pulling elements are either rigid or non-rigid, but reinforced with a rigid element. The examiner contends that such selection of the rigid characteristic is an obvious design choice which does not patentably distinguish applicant's invention absent a critical teaching.

9. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Prellar in view of U.S. Patent No. 5,425,702 ("Carn et al.").

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Regarding claim 13, Prellar fails to teach alignment marks. However, it is well known in the art to provide alignment marks on a device to be used on the human body in order to determine proper placement of a device, as evidenced by Carn et al. Although Carn et al. is not a wound closure device, the Carn et al. teach it is conventional to place line markings (indica) on device to be used on the human body for the purpose of determining proper placement of the device on a user. It would have been obvious to one having ordinary skill in the art to modify Prellar with alignment marks or any other form of indicia for the purpose of determining proper placement of the device on the user, as suggested by Carn et al.

10. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson in view of U.S. Patent No. 5,779,659 ("Allen").

Regarding claims 15 and 16, Peterson fails to teach elastic tension indicators. However, Allen teaches it is conventional in the art to provide elastic bandages with tension indicators for the purpose of indicating the amount of tension being applied to the bandage. It would have been obvious to one having ordinary skill in the art to modify Peterson with a tension indicator provided on the bandage including the removable protectors for the purpose of indicating the amount of tension applied to the user, as suggested by Allen.

*Response to Arguments*

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11. Applicant's arguments with respect to Peterson and Roomi have been considered but are moot in view of the new ground(s) of rejection.

As regards applicant's arguments that the connectors are not directly attached to the first and second strips, the examiner contends that the term "directly" is not present in the claims. Even if the term directly was placed in the claims the examiner contends that the specification fails to address the criticality of such a feature. Also, the examiner contends that the prior art devices of Peterson and Prellar perform equally well.

Any inquiry concerning this communication should be directed to Kim M. Lewis at telephone number (703) 308-1191.

kml  
April 2, 2001



KIM M. LEWIS  
PRIMARY EXAMINER  
AU 3761